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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,860	09/30/2003	Yoshimi Kikuchi	US-111	1661

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EXAMINER	
VOGEL, NANCY S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/673,860	KIKUCHI ET AL.	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-12* is/are pending in the application.

4a) Of the above claim(s) *5,6,9 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 4, 7, 8, 10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 5, 6, 9 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/24/04.

It is noted that applicants request in their response filed 3/9/05, that claim 12 be examined, sin "[t]his claim is directed to the species of signal peptide elected by applicants, that is SEQ ID NO:3". However, claim 12 reads "a sequence having at least one replacement, deletion, addition or insertion of an amino acid, or a combination thereof in the amino acid sequence of SEQ ID NO:3" and therefore, is not drawn to the method of claim 7 wherein the signal peptide is that shown in SEQ ID NO:3, as elected. Therefore the claim has not been examined in the present Office action. It is noted that the claim was also not examined in the previous Office action mailed 12/23/04.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 4, 7, 8, 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained essentially for the reasons set forth in the previous Office action, in slightly modified form, made necessary by applicant's amendments to the claims.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claim 1 is drawn to a method for producing a heterologous protein comprising culturing a Corynebacterium glutamicum AJ12036 bacterium or mutant thereof wherein said bacterium or mutant thereof is able to secrete the heterologous protein at least 2-fold higher than C. glutamicum ATCC13869 having the same genetic expression construct. Claim 3 specifies that the mutant does not produce a cell surface protein. Claim 4 specifies that the signal peptide comprises a signal peptide of a cell surface protein from a coryneform bacterium, and claim 7 recites that the signal peptide is from a cell surface protein from C. ammoniagenes. Dependent claims 10 and 11 recite culture conditions. The specification discloses that mutants may include any strains obtained by mutagenesis and selection procedures for increased secretory properties (page 10 of the specification). The specification further discloses that such that they do not produce surface proteins (page 10). The specification further discloses that the signal peptide of any surface protein of Coryneform bacteria is encompassed by the signal peptide recited in the claims. Claims 1, 3, 4, 7, 8, 10 and 11 are genus claims in terms of (1) a method using C. glutamicum AJ12036 or any mutant thereof which secretes a heterologous protein at levels 2-fold higher when compared to wild type C. glutamicum

ATCC 13869 (claims 1, 3, 4, 7, 8, 10, 11); (2) a method using AJ12036 or any mutant thereof which secretes a heterologous protein at levels 2-fold higher when compared to wild type C. glutamicum ATCC 13869, and which does not produce a cell surface protein (claim 3). Thus, the claims encompass a broad class of methods using mutant strains of coryneform bacterium having increased secretory properties, and said mutants which also do not have a surface protein. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the methods utilizing the encompassed mutant coryneform bacteria, based on the teachings of the specification. While the specification provides broad guidance on methods of mutagenesis and selection which may be used to isolate mutant bacteria, there is no disclosure of the precise mutations of the AJ12036 coryneform bacteria useful for obtaining and/or maintaining the recited increased secretion properties. There is no structure-function analysis on the disclosed strain of C. glutamicum AJ12036, or characterization of the mutation(s) contained therein, which result in the desired properties. It cannot be determined what mutations would need to be present, or which gene sequences which would need to be maintained, in order to result in the claimed increased secretion properties. The recitation in the claims and specification of methods utilizing mutant bacterial strains which are waiting to be discovered, does not satisfy the written description requirement.

Therefore, the specification does not describe the claimed method utilizing mutant coryneform bacteria having increased secretory properties in such full, clear,

concise and exact terms so as to indicate that applicant had possession of the invention recited in the claims at the time of filing the present application.

Vas-Cath V. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of methods utilizing mutant coryneform bacteria, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Col. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the disclosed methods using the strain AJ12036, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. 112, first

paragraph. Applicant is reminded that *Vas-Cath* makes clear that written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Applicant's arguments filed 3/9/05 have been fully considered but they are not persuasive.

Applicants have argued that the claims have been amended to recite that the claimed method utilizes the C. glutamicum AJ12036 or a mutant thereof which has been transformed with the recited genetic expression construct, and as a result, is able to secrete a heterologous protein 2-fold higher when compared with the C. glutamicum ATCC 13869. Applicants state that "it would be expected that a mutant of AJ12036 would not lose the ability to secrete heterologous protein in high capacity, similar to the parent AJ12036 since one of ordinary skill in the art would known that random mutations rarely introduce a mutation in the region responsible for the secretion ability" (page 4 of the remarks). Applicants also point to page 10 of the specification which describes "examples of mutants from AJ12036, and also a mutant which does not produce cellular surface proteins" . However, it is maintained that the claims as drafted encompass any mutant of the AJ12036 strain, and since there is no description of the location and/or types of mutations which would result in the recited function, i.e. there is no structural information regarding the identity of the encompassed mutant strains, the application fails to provide an adequate written description of the invention as now claimed. A single mutant does not constitute such a description. Therefore, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TERRY MCKELVEY
PRIMARY EXAMINER